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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,242	06/07/2000	Jorg Priewe	GYN-0045	9991

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Audley A Ciamporcero Jr Esq
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

EXAMINER

ROBERTS, PAUL A

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 08/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/589,242

Applicant(s)

PRIEWE ET AL.

Examiner

Paul A Roberts

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 June 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 8 should have its elements relisted as a-f in opposed to g-l. Those elements will be referred to as the renumbered elements just mentioned.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the structure of the inflatable member and its various embodiments as described in the specification. Figure 4a-5c are of very poor photocopy quality, they also very little detail of the structure described by the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: There is no figure 16d, 32a in the drawings yet the spec refers to them. A proposed drawing correction or

corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Regarding claim 1,3,5 the phrase "needle-like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "needle-like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).
4. Regarding claim 3 the phrase "suture-like" renders the claim indefinite. The use of like as a modifier requires the exact breath of the claim to be recited in the specification or drawings. Since, a description of what is to be considered suture-like or needle-like is not given, the exact breath of the claims cannot be ascertained.
5. Regarding claim 1 the descriptive words of "adjusting means" are ambiguous because there are two adjusting means described in the specification. 35 USC 112 requires that the applicant distinctly point out the subject matter. Please elaborate whether the means refers to the ability to shift the tape by pulling on either side of the tape, or if the applicant is describing inflating/deflating the inflatable member.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1,3, 6, 7 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Claren et al 5899909.

6. Regarding claim 1, Claren teaches a surgical device to use for ceasing female incontinence. His device has a tape with an adjusting means. The tape itself is the adjusting means since has threads that allow it to be adjusted once it has been implanted. Additionally, the tape can be adjusted after has been implanted via either side of the tape can be pulled as shown in figure 11 to help secure the tape, immediately following the implantation.

Furthermore, Claren teaches that his instrument uses a curved needle with a curved shaft and that it has a means to be attached to the tape. Figure 7

7. Regarding claim 3, the use of “suture-like” renders this claim indefinite, however, as best interpreted a “suture-like” line has the following properties. “A synthetic based line that is minimally reactive in biological tissue. Commonly used are nylon, PROLENE® and gut. Absorbable suture will dissolve over time (Vicryl and chromic).” (Quoted from <http://cancerweb.ncl.ac.uk/>, an online medical dictionary.) Claren recites that “a suitable material for the tape is PROLENE®, ” column 4 line 35. Therefore the adjusting means, the thread of the tape, is “suture-like” and it passes through the tape as illustrated in figure 17.

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8. Regarding claim 6, Claren teaches the tape can be a material that is similar in structure to a suture. Figure 7 clearly shows the structure of tape similar to the one diagramed in figure 2a by the applicant. Claren clearly demonstrates all of the 4 following steps including:

- The use of a two, curved needle system with tape (figures 4-11).
- passing the needle and tape through the body via the vagina in order to form a sling around the vagina, in figure 4-11 (particularly figure 11.)
- Parts c and d are described clearly in the last claim of the patent where Claren states
 - the straps should be tightened/adjusted (part c) (claim 32, figure 11) and
 - the straps should be left implanted in the body (part d) (claim 32.)

9. Regarding claim 7. Claim 7 is rejected under 35 USC 102(e) as being unpatentable over Claren for the reasons mentioned in the rejection of claim 6 and for the following reasons.

- Claren teaches a device where the tape needs to be attached to the needles (figure 4.)
- Claren teaches the strap/tape should be tightened/adjusted after placement (claim 32.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 1, 2, 4, 5, 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claren et al 5899909 in view of Gil-Vernet 6117067, as best understood.

11. Regarding claims 1 & 2, Claren's device teaches a tape and curved needle member with a means to attach the tape to the needle, yet fails to teach the use of an inflatable member for "adjusting the tape after implantation." However, Gil-Vernet teaches that an inflatable member can be secured to the strings of an incontinence device for the purpose of adjusting the placement of the device post-operatively. He further teaches that the adjusting means is expandable (col 4 line 25-30.) It would have been obvious to one skilled in the art at the time of the invention to equip the Claren device with the inflatable/expandable member attachment for the purpose of allowing the device to be adjusted after the device had been implanted.

12. Regarding claim 4, all devices have distal and proximal ends. Claren's device has two needles with a curved shaft where the needles are attached together by tape. It would have been obvious to one skilled in the art at the time of the invention to attach the inflatable device taught by Gil-Vernet onto the Claren device for the purpose of allowing the device to be adjusted after the device had been implanted.

13. Regarding claim 5 & 8. The modified Claren device teaches a surgical method utilizing two curved needles and a tape attached between them, where the tape has an inflatable member attached for receiving a bulking agent (part a – claim 5 & 8.) Furthermore he shows that the tape should be connected to the needles in figure 4 (part b - claim 8.) The method Claren teaches is as follows:

- passing a tape into the body via the vagina first at one end thereof and then at the other end thereof at one side and the other, respectively, of urethra to form a loop around urethra, located between urethra and the vaginal wall (part b-claim 5, part c - claim 8.)

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- extending said tape over the pubic bone and through the abdominal wall, the ends of the tape being available outside the abdominal wall (part c - claim 5, part d claim 8.) Also note figure 11 shows that a sling is actually formed with regard to applicants claim 8.
- tightening said strap at said ends, and
- leaving the tape implanted in the body. (part d – claim 5 part e – claim 8)

One should note that in this claim Claren does not specify that he use needles as the instrument in which the surgeon should use to pass the tape around the urethra. However, Claren clearly illustrates this is the desired method through the use of diagrams in figures 4-11.

Regarding part e- claim 5 and part f- claim 8, Claren does not teach the method of inflating the bulking member, however the step is inherent in the modified Claren device. Furthermore Gil-Vernet particularly points out this step in his incontinence member in lines 50-57, where Gil-Vernet teaches that the device can be inflated for the “purpose of increasing the distance that separates the upper and lower chamber... (whereby) the said effects will ... result in a tensioning or slackening of the threads(/tape.)” It would have been obvious to one skilled in the art at the time of the invention to employ the method used by Claren and combine it with the step of inflating the inflatable member for the purpose of changing the tension of the tape slung around the urethra.

14. Regarding claim 9,

- Claren teaches “In the preferred embodiment the tape comprises a mesh or netting forming openings of the order of 1 mm” (lines 30-38 col 4.)
- Gil-Vernet teaches “in particular a liquid, inside it in a variable amount” (line 4, col 6.)

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- Gil-Vernet teaches that the expandable chamber should be positioned between the tape and the anatomical structure (figure 1.)

It would have been obvious to one skilled in the art at the time of the invention to utilize the mesh tape taught by the modified Claren device so that it includes the mesh tape and allows for a variable amount of liquid to be moved into an expandable chamber to enable the surgeon to more easily adjust the surgical device.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


US Pat #	Reason for inclusion
5836315	method of suspending tissue mass
6042534	stabilization sling
5611515	method of bladder suspension
5112344	needle and tape structure
5080667	curved needle
5582188	method of suspending tissue mass
5741299	needle assembly
5836315	method of suspending tissue mass

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts
August 7, 2002


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700